

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Comparison of the effectiveness of adipose-derived stem cell conditioned medium (ADSC\_CM) combined with microneedling or fractional carbon dioxide laser on acne scar healing

#### Protocol summary

##### Study aim

Evaluation the effect of conditioned medium of adipose derived stem cells on healing of scar after fractional Carbon Dioxide(CO2) laser resurfacing or micro needling

##### Design

The aim of this study was to evaluate the efficacy and side effects of using CO2 laser with conditioned medium in comparison with microneedling with conditioned medium in 30 patients with acne scars who were enrolled in block randomized method. In each session immediately after laser treatment, one side of the patient's face (intervention group) conditioned media of adipose derived stem cells, and the other side of the face (control group) physiological serum is applied topically on the laser site for one hour. This procedure is repeated 4 times with 4 week intervals.

##### Settings and conduct

This design is done at the skin and stem cell research center of Tehran university of medical sciences and without the patient's knowledge, after the CO2 laser or microneedling, one side of the face of conditioned media of ADSC and other side for blinding is used of the physiology serum in the scars.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 20-60; Developing middle to severe atrophic scars in face region. Exclusion criteria: Pregnancy and breastfeeding; Active infection in face; Using any local drugs on face except sun protection creams in last month

##### Intervention groups

Intervention group 1: The whole face is treated with CO2 laser. Immediately, on one side of the face, the conditioned media of adipose derived stem cells, and on the other side of the face, physiological serum is applied topically to the scar site. Intervention group 2: The whole face is treated with microneedling. Then, similar to the

first intervention group, conditioned medium and physiological serum are used on both sides of the face.

##### Main outcome variables

scar's surface; side effects; patient's satisfaction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20080901001159N33**

Registration date: **2021-06-01, 1400/03/11**

Registration timing: **prospective**

Last update: **2021-06-01, 1400/03/11**

Update count: **0**

##### Registration date

2021-06-01, 1400/03/11

##### Registrant information

##### Name

Mohamad Ali Nilforoushzadeh

##### Name of organization / entity

Skin and Stem Cell Research Center, Tehran

University of Medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2220 5158

##### Email address

sdLrc@mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-06-22, 1400/04/01

##### Expected recruitment end date

2021-08-23, 1400/06/01  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Comparison of the effectiveness of adipose-derived stem cell condition medium (ADSC\_CM) combined with microneedling or fractional carbon dioxide laser on acne scar healing

**Public title**  
Evaluation the effect of conditioned media of adipose driven stem cells on acne scar

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Age between 20-60 Having middle to severe atrophic scar in face region

**Exclusion criteria:**

Pregnancy and breastfeeding History of cancer  
Pregnancy, breastfeeding Patients with active acne  
Vascular / muscle collagenous disorders of immunodeficiency or use of immunosuppressive drugs  
People with herpes disease are active People with Mental Disorders Active infection in the face

**Age**

From **20 years** old to **60 years** old

**Gender**

Both

**Phase**

1

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **30**  
More than 1 sample in each individual  
Number of samples in each individual: **2**  
A half face will be considered as the control group and one half as an intervention group

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this method, block randomization is used. Each patient was considered as a block and left and right sides of their face were randomly assigned to two groups using cards with study groups written on them.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In each group, both sides of the face will be treated with CO2 laser or microneedling at the patient's scar area, immediately on one side of the face, the conditioned media of adipose derived stem cells and the other side of the face saline solution is used topically on the scar.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

**Street address**

Tehran University of Medical Sciences, Keshavarz blvd

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Approval date**

2021-02-14, 1399/11/26

**Ethics committee reference number**

IR.TUMS.MEDICINE.REC.1399.1131

**Health conditions studied**

1

**Description of health condition studied**

atrophic scar

**ICD-10 code**

L90.5

**ICD-10 code description**

Scar conditions and fibrosis of skin

**Primary outcomes**

1

**Description**

Scar size

**Timepoint**

before and 3month after the intervention

**Method of measurement**

visioface

2

**Description**

side effects

**Timepoint**

One week after session

**Method of measurement**

Questionnaire and visit

### 3

#### **Description**

Patient Satisfaction

#### **Timepoint**

Three and six months after the last treatment session

#### **Method of measurement**

Questionnaire

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

#### **Description**

Intervention group: One side of the face after being anesthetized, is first treated with Fractional Laser Co2, and then adipose conditioned media of adipose derived stem cells is applied topically to the scars for one hour. This procedure is repeated 4 times with intervals of 4 weeks.

#### **Category**

Treatment - Other

#### 2

#### **Description**

Intervention group: One side of the face after being anesthetized, is first treated with microneedling, and then adipose conditioned media of adipose derived stem cells is applied topically to the scars for one hour. This procedure is repeated 4 times with intervals of 4 weeks.

#### **Category**

Treatment - Other

#### 3

#### **Description**

Control group: (Other side of face) After sufficient anesthesia, first treatment with Fractional Laser Co2, and then physiological serum is applied topically to the site of the scars for one hour. This procedure is repeated 4 times with intervals of 4 weeks.:

#### **Category**

Treatment - Other

#### 4

#### **Description**

Control group: (Other side of face) After sufficient anesthesia, first treatment with microneedling, and then physiological serum is applied topically to the site of the scars for one hour. This procedure is repeated 4 times with intervals of 4 weeks.

#### **Category**

Treatment - Other

### **Recruitment centers**

#### 1

#### **Recruitment center**

##### **Name of recruitment center**

Clinics of Skin and Stem cell Research Center of Tehran University of Medical Sciences

##### **Full name of responsible person**

Maryam nouri

##### **Street address**

No 4, Maryam Alley, South Kamraniyeh Street, Tehran, Iran

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1937957511

##### **Phone**

+98 21 2221 5558

##### **Email**

m.nouri3023@gmail.com

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

##### **Name of organization / entity**

Tehran University of Medical Sciences

##### **Full name of responsible person**

Abbas Ali Karimi

##### **Street address**

Tehran University of Medical Sciences, Keshavarz blvd

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1417653761

##### **Phone**

+98 21 81631

##### **Email**

tums\_edu@tums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Tehran University of Medical Sciences

#### **Proportion provided by this source**

100

#### **Public or private sector**

Public

#### **Domestic or foreign origin**

Domestic

#### **Category of foreign source of funding**

empty

#### **Country of origin**

#### **Type of organization providing the funding**

Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Skin and Stem cell Research Center of Tehran  
University of Medical Sciences

**Full name of responsible person**

Maryam Nouri

**Position**

Researcher

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

No 4, Maryam Alley, South Kamraniyeh Street,  
Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1937957511

**Phone**

+98 21 2223 9387

**Email**

m.nouri3023@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Skin and Stem cell Research Center of Tehran  
University of Medical Sciences

**Full name of responsible person**

Mohammad Ali Nilforoushzadeh

**Position**

Professor

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dermatology

**Street address**

No 4, Maryam Alley, South Kamraniyeh Street,  
Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

+98 901 588 6740

**Phone**

+98 21 2223 9387

**Email**

nilforoosh@sina.tums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Skin and Stem cell Research Center of Tehran  
University of Medical Sciences

**Full name of responsible person**

Mona mahmoubbeyk

**Position**

Researcher

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Cell Developmental Biology

**Street address**

No 4, Maryam Alley, South Kamraniyeh Street,  
Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1937957511

**Phone**

+98 21 2221 5558

**Email**

mmahmoubbeyk@yahoo.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable